Ticagrelor monotherapy beyond one month after PCI in ACS or stable CAD in elderly patients: a pre-specified analysis of the GLOBAL LEADERS trial

Tomaniak, Mariusz ; Chichareon, Ply ; Modolo, Rodrigo ; Takahashi, Kuniaki ; Chang, Chun Chin ; Kogame, Norihiro ; Spitzer, Ernest ; Buszman, Pawel E ; van Geuns, Robert-Jan M ; Valkov, Veselin ; Steinwender, Clemens ; Geisler, Tobias ; Prokopczuk, Janusz ; Sabaté, Manel ; Zmudka, Krzysztof ; Rademaker-Havinga, Tessa ; Tijssen, Jan G P ; Jüni, Peter ; Hamm, Christian ; Steg, Philippe Gabriel ; Onuma, Yoshinobu ; Vranckx, Pascal ; Valgimigli, Marco ; Windecker, Stephan ; Baber, Usman ; Anderson, Richard ; Dominici, Marcello ; Serruys, Patrick W

Abstract: AIMS Antiplatelet treatment in the elderly post percutaneous coronary interventions (PCI) remains a complex issue. Here we report the results of the pre-specified subgroup analysis of the GLOBAL LEADERS trial evaluating the long-term safety and cardiovascular efficacy of ticagrelor monotherapy among patients categorised according to the pre-specified cut-off value of 75 years of age. METHODS AND RESULTS This was a pre-specified analysis of the randomised GLOBAL LEADERS trial (n=15,991), comparing 23-month ticagrelor monotherapy (after one month of DAPT) with the reference treatment (12-month DAPT followed by 12 months of aspirin). Among elderly patients (>75 years; n=2,565), the primary endpoint (two-year all-cause mortality or new Q-wave core lab-adjudicated myocardial infarction [MI]) occurred in 7.2% and 9.4% of patients in the ticagrelor monotherapy and the reference group, respectively (hazard ratio [HR] 0.75, 95% confidence interval [CI]: 0.58-0.99, p=0.041; pint=0.23); BARC-defined bleeding type 3/5 occurred in 5.2% and 4.1%, respectively (HR 1.29, 95% CI: 0.89-1.86; p=0.180; pint=0.06). The elderly with stable CAD had a higher rate of BARC 3/5 type bleeding (HR 2.05, 95% CI: 1.18-3.55) with ticagrelor monotherapy versus the reference treatment (pint=0.02). Elderly patients had a lower rate of definite or probable stent thrombosis (ST) with ticagrelor monotherapy (0.4% vs 1.4%, p=0.015, pint=0.01), compared with the reference group. CONCLUSIONS In this pre-specified, exploratory analysis of the overall neutral trial, there was no differential treatment effect of ticagrelor monotherapy (after one-month dual therapy with aspirin) found in elderly patients undergoing PCI with respect to the rate of the primary endpoint of all-cause death or new Q-wave MI. The lower rate of ST in the elderly with ticagrelor monotherapy is hypothesis-generating. ClinicalTrials.gov identifier: NCT01813435.

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CORONARY INTERVENTIONS

Ticagrelor monotherapy beyond one month after PCI in ACS or stable CAD in elderly patients: a pre-specified analysis of the GLOBAL LEADERS trial

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Mariusz Tomaniak[1,2], MD; Ply Chichareon[3,4], MD; Rodrigo Modolo[3,5], MD; Kuniaki Takahashi[3], MD; Chun Chin Chang[1], MD; Norihiro Kogame[3], MD; Ernest Spitzer[1,6], MD; Pawel E. Buszman[7], MD, PhD; Robert-Jan M. van Geuns[1,8], MD, PhD; Veselin Valkov[9], MD; Clemens Steinwender[10], MD, PhD; Tobias Geisler[11], MD, PhD; Janusz Prokopczuk[12], MD, PhD; Manel Sabaté[13], MD, PhD; Krzysztof Zmudka[14], MD, PhD; Tessa Rademaker-Havinga[6], MSc; Jan G.P. Tijssen[3,6], PhD; Peter Jüni[15], MD, PhD; Christian Hamm[16], MD, PhD; Philippe Gabriel Steg[17], MD, PhD; Yoshinobu Onuma[18], MD, PhD; Pascal Vranckx[19]; Marco Valgimigli[20], MD, PhD; Stephan Windecker[20], MD, PhD; Usman Baber[21], MD, PhD; Richard Anderson[22], MD, PhD; Marcello Dominici[23], MD, PhD; Patrick W. Serruys[18], MD, PhD

1. Department of Cardiology, Erasmus Medical Center, Rotterdam, the Netherlands; 2. First Department of Cardiology, Medical University of Warsaw, Warsaw, Poland; 3. Amsterdam UMC, Amsterdam, the Netherlands; 4. Division of Cardiology, Department of Internal Medicine, Prince of Songkla University, Songkhla, Thailand; 5. Department of Internal Medicine, Cardiology Division, University of Campinas (UNICAMP), Campinas, Brazil; 6. Cardialysis Core Laboratories and Clinical Trial Management, Rotterdam, the Netherlands; 7. PAKS Dabrowa, Dabrowa Gornicza, Poland; 8. Department of Cardiology, Radboud UMC, Nijmegen, the Netherlands; 9. "St. Marina" University Hospital, Varna, Bulgaria; 10. Department of Cardiology, Medical Faculty, Johannes Kepler University, Linz, Austria; 11. Uniklinikum Tübingen, Tübingen, Germany; 12. PAKS Kozle, Kedzierzyn-Kozle, Poland; 13. Clinic Hospital Barcelona, Barcelona, Spain; 14. Krakowski Szpital Specjalistyczny im. Jana Pawła II, Krakow, Poland; 15. Applied Health Research Centre, Li Ka Shing Knowledge Institute, St Michael's Hospital, University of Toronto, Toronto, Canada; 16. University of Giessen, Giessen, Germany; 17. FACT, Université Paris Diderot, Hôpital Bichat, Assistance Publique-Hôpitaux de Paris, Paris, France; 18. Department of Cardiology, National University of Ireland, Galway (NUIG), Galway, Ireland; 19. Department of Cardiology and Critical Care Medicine, Hartcentrum Hasselt, Jessa Ziekenhuis, Hasselt, Belgium; 20. Department of Cardiology, Bern University Hospital, Inselspital, University of Bern, Bern, Switzerland; 21. Mount Sinai Heart, Mount Sinai Medical Center, New York, NY, USA; 22. University Hospital of Wales, Cardiff, United Kingdom; 23. Azienda Ospedaliera S. Maria, Terni, Italy

Aims: Antiplatelet treatment in the elderly post percutaneous coronary interventions (PCI) remains a complex issue. Here we report the results of the pre-specified subgroup analysis of the GLOBAL LEADERS trial evaluating the long-term safety and cardiovascular efficacy of ticagrelor monotherapy among patients categorised according to the pre-specified cut-off value of 75 years of age.

Methods and results: This was a pre-specified analysis of the randomised GLOBAL LEADERS trial (n=15,991), comparing 23-month ticagrelor monotherapy (after one month of DAPT) with the reference treatment (12-month DAPT followed by 12 months of aspirin). Among elderly patients (>75 years; n=2,565), the primary endpoint (two-year all-cause mortality or new Q-wave core lab-adjudicated myocardial infarction [MI]) occurred in 7.2% and 9.4% of patients in the ticagrelor monotherapy and the reference group, respectively (hazard ratio [HR] 0.75, 95% confidence interval [CI]: 0.58-0.99, p=0.041; p_{int}=0.23);

p_{int}=0.06). The elderly with stable CAD had a higher rate of BARC 3/5 type bleeding (HR 2.05, 95% CI: 1.16-3.55) with ticagrelor monotherapy versus the reference treatment (p_{int}=0.02). Elderly patients had a lower rate of definite or probable stent thrombosis (ST) with ticagrelor monotherapy (0.4% vs 1.4%, p=0.015, p_{int}=0.01), compared with the reference group.

Conclusions: In this pre-specified, exploratory analysis of the overall neutral trial, there was no differential treatment effect of ticagrelor monotherapy (after one-month dual therapy with aspirin) found in elderly patients undergoing PCI with respect to the rate of the primary endpoint of all-cause death or new Q-wave MI. The lower rate of ST in the elderly with ticagrelor monotherapy is hypothesis-generating. ClinicalTrials.gov identifier: NCT01813435

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